

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF NORTH CAROLINA
No. 1:18-cv-00502-WO-JLW**

LLOYD BUFFKIN, et al.,

Plaintiffs,

v.

ERIK HOOKS, et al.,

Defendants.

**SUPPLEMENTAL
CLASS ACTION
COMPLAINT**

1. Plaintiffs filed their class action complaint on June 15, 2018, alleging that Defendants’ policies and practices concerning the screening, monitoring, and treatment of hepatitis C (“HCV”) in state prisons violated the Eighth Amendment and the Americans with Disabilities Act. (Doc. 1).
2. With the exception of requests for class certification and a preliminary injunction, and allegations concerning treatment of the named Plaintiffs with DAAs, Plaintiffs incorporate by reference all allegations from the initial complaint.
3. On March 20, 2019, the Court certified a class of “all current and future prisoners in DPS custody who have or will have chronic hepatitis C virus and have not been treated with direct-acting antiviral drugs” (“the Plaintiff Class”). (Doc. 55 at 35).
4. The Court also enjoined operation of policy CP-7, which governed the screening, monitoring, and treatment of HCV for all class members.

5. Later that month, Defendants enacted an interim version of CP-7 (the “interim policy”). (Doc. 52-1). The interim policy also governs the screening, monitoring, and treatment of HCV for all class members.
6. Plaintiffs’ expert, Dr. Andrew Muir, filed an affidavit opining as to how the interim policy did not meet the applicable standard of medical care and created risks of harm for members of the Plaintiff Class. (Doc. 54).
7. Then-DPS Medical Director Anita Wilson was responsible for creating and implementing the interim policy.
8. The interim policy’s screening provisions are nearly identical to the previous policy. Instead of providing for screening of everyone admitted into state custody, Defendants only screen for certain risk factors or upon a patient’s request.
9. Defendants know that risk-based screening has resulted in a failure to diagnose many HCV-positive people in their custody, but they have maintained the practice anyway.
10. When a patient receives an HCV diagnosis, the interim policy refers consideration of treatment to an HCV committee.
11. The committee meets monthly to determine if HCV patients should undergo additional lab tests and/or receive DAA therapy.
12. The interim policy adopts guidance from the Federal Bureau of Prisons (“FBOP”), but does not state what criteria the FBOP guidance uses.

13. The FBOP guidance determines a patient's treatment priority primarily on the AST to Platelet Ratio Index ("APRI").¹ The APRI predicts the degree of fibrosis and utilizes two common laboratory tests (aspartate aminotransferase (AST) and the platelet count) that are part of the routine assessment of patients with HCV. The formula for the APRI score is:

$$\frac{(\text{AST/AST upper limit of normal}) \times 100}{\text{platelet count (10}^9\text{/L)}}$$

14. The FBOP guidance places HCV patients into three levels of priority for DAA therapy.

15. Patients in the first level receive highest priority for treatment. To qualify, a patient must have an APRI score of 2.0 or higher, Metavir or Batts/Ludwig stage 3 or 4 on liver biopsy, or known or suspected cirrhosis.

16. Patients in the second level must have an APRI score greater than or equal to .7, or stage 2 fibrosis on liver biopsy.

17. All other patients fall into the third and lowest priority level.

18. The FBOP guidance does not guarantee treatment for anyone or establish any kind of timeline in which even the sickest patients must receive treatment.

¹Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection, Federal Bureau of Prisons Clinical Guidance (Jan. 2018), https://www.bop.gov/resources/pdfs/012018_hcv_infection.pdf.

19. Moreover, an APRI score, like a FibroSure test, may produce inaccurate results. Research has found that the APRI score can predict the degree of fibrosis, but various cutoff values alter the test characteristics. The FBOP guidance lists an APRI score of 2.0 as the cutoff for cirrhosis. A meta-analysis of 40 studies found that the cutoff of 2.0 had sensitivity of 46% and specificity of 91%. Thus, the cutoff of 2.0 would likely identify less than half of the patients with cirrhosis. If a cutoff of 1.0 is used, that study found the sensitivity improved to 76% with specificity of 72%. The cutoff of 1.0 would therefore identify more patients with cirrhosis.²

20. For these reasons, the interim policy creates substantial risks that Plaintiff Class members will never receive a diagnosis, or that they will only receive a diagnosis after they begin to experience painful and potentially deadly effects of advanced HCV. And for those diagnosed, the interim policy creates substantial risks that they will either be erroneously denied treatment, or that they will have to wait indefinitely as their condition deteriorates.

21. The minimal resources Defendants have devoted to HCV treatment exacerbate these risks.

22. Defendants employ a single hepatologist who operates the only DPS liver clinic at Central Prison in Raleigh. The hepatologist works just 12 hours a week. In that day-and-a-half, the hepatologist is not just responsible for treating HCV, but all kinds of liver conditions.

² Lin ZH, Xin YN, Dong QJ, et al. Performance of the aspartate aminotransferase-to-platelet ratio index for the staging of hepatitis C-related fibrosis: an updated meta-analysis. *Hepatology*. 2011;53(3):726.

23. Defendants have estimated that between approximately 5,000 and 12,000 people in their custody have HCV.

24. Thus, because Defendants have devoted such minimal resources to such an enormous problem, Plaintiff Class members face even greater risks of suffering serious harm from untreated HCV.

CAUSES OF ACTION

Count I – Eighth Amendment to the U.S. Constitution, via 42 U.S.C. § 1983

25. Defendants know of and enforce the policies and practices described above. Plaintiff Class members have an objectively serious medical need in the form of chronic HCV. Defendants know of and have known of these needs, but intentionally refuse to provide screening and treatment addressing those needs. Defendants know that failure to treat those serious medical needs has harmed Plaintiff Class members and continues to place them at substantial risk of serious harm.

26. Defendants' conscious disregard of the risks facing the Plaintiff Class constitutes deliberate indifference and violates the evolving standards of decency that mark the progress of a maturing society.

Count II – Americans with Disabilities Act, 42 U.S.C. § 12131, et seq.

27. The Americans with Disabilities Act (ADA) prohibits public entities from discriminating against persons with disabilities in their programs, services, and activities. 42 U.S.C. §§ 12131–12134.

28. The ADA defines “public entity” as any state or local government or “any department, agency . . . or other instrumentality” of a state or local government. 42 U.S.C. § 12131(1)(A), (B).

29. Defendant DPS is a “public entity” under the ADA.

30. Each member of the Plaintiff Class has a disability under the ADA.

31. Each member of the Plaintiff Class is “a qualified individual with a disability” under the ADA because they meet the essential eligibility requirements for the receipt of services or participation in programs or activities provided by DPS, except that they require reasonable modifications to rules, policies, or practices, the removal of barriers, or the provision of auxiliary aids and services.

32. DPS discriminates against the Plaintiff Class in violation of the ADA by withholding medically necessary treatment that will likely cure their disability, while not withholding medically necessary treatment from individuals with different disabilities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court issue the following relief:

- a. A declaratory judgment that Defendants’ policies and practices concerning the diagnosis, monitoring, and treatment of chronic HCV violate the Eighth Amendment and ADA.
- b. A permanent injunction ordering Defendants to: (i) formulate and implement an HCV treatment policy that meets the current standard of medical care, including identifying all members of the Plaintiff Class; (ii) treat members of the Plaintiff Class with appropriate DAAs; (iii) provide members of the Plaintiff Class an

appropriate and accurate assessment of their level of fibrosis or cirrhosis, counseling on drug interactions, and ongoing medical care for complications and symptoms of HCV; and (iv) any further appropriate injunctions to prevent future violations of the Plaintiff Class's rights.

- c. Award Plaintiffs' costs, including reasonable attorneys' fees.
- d. Allow any further relief to which the Plaintiff Class may be entitled.

Respectfully submitted, this 16th day of October, 2019.

/s/ Daniel K. Siegel

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